

REMARKS**Claim Rejections under 35 USC § 112, para. 2 - Indefiniteness**

Claims 1-17 stand rejected under 35 U.S.C. § 112, second paragraph because the phrases "solvents of the first type" and "solvents of the second type" are held indefinite and ambiguous. Claim 1 is amended such that "the solvent of the first type" is *a chlorinated solvent selected from the group consisting of chloroform and methylene chloride, a polar solvent selected from the group consisting of dimethyl formamide and dimethyl sulfoxide, or a mixture thereof.* Support for this amendment may be found on p. 5, lines 20-21 of the specification. As amended, claim 1 particularly points out and clearly claims the subject matter of the invention. Reconsideration of claim 1 and withdrawal of the 35 U.S.C. § 112, second paragraph objection to claims 1-17 is therefore requested.

Claim Rejections under 35 USC § 103(a) - Obviousness

Claims 1-17 are rejected under 35 USC § 103(a) as being unpatentable over Kumar et al. (US 6,528,660) for reasons of obviousness. As amended, claim 1 provides for a solvent of the first type that is "a chlorinated solvent selected from the group consisting of chloroform and methylene chloride, a polar solvent selected from the group consisting of dimethyl formamide and dimethyl sulfoxide, or a mixture thereof". Kumar does not disclose such chlorinated solvents or polar solvents, but rather, discloses only a "non-hydroxylic solvent, e.g. tetrahydrofuran" as being able to dissolve crystalline atorvastatin. (see Kumar, col. 2, lines 19-20, 42-43, and 57-58, Abstract). In particular, every Example discloses only tetrahydrofuran for dissolving crystalline atorvastatin (see col. 3, Example 1, Method A, lines 42-44 and Method B,

lines 54-56; and col. 4, Example 2, lines 15-16, and Example 3, lines 27-28). Thus amended claim 1 is not obvious in light of Kumar, since amended claim 1 teaches the use of a chlorinated solvent that is specifically chloroform or methylene chloride, a polar solvent that is specifically dimethyl formamide or dimethyl sulfoxide, or mixtures thereof, as the first-type solvent. In contrast, Kumar specifically requires only a non-hydroxylic solvent (i.e., a non-polar solvent) and discloses only tetrahydrofuran as the working example for the first solvent. Kumar makes no mention or suggestion of the use of the specific chlorinated solvents, specific non-polar solvents, or mixtures thereof required in the presently claimed invention for the first-type solvent.

To have a *prima facie* case of obviousness, three basic criteria must be met, according to MPEP § 2142. First, there must be some suggestion or motivation, in the cited reference or knowledge generally available in the art, to modify the reference. Second, there must be a reasonable expectation of success. And third, the prior art reference must teach all the elements of the claimed invention. In the present case, there is no suggestion to modify the solvents disclosed in Kumar to those required in the presently claimed invention for the first-type solvent, nor is there any motivation in the art generally available to arrive at the specifically-claimed chlorinated solvents, non-polar solvents and mixtures thereof for the first-type solvent. Moreover, all the elements of the presently claimed invention are not taught or suggested by Kumar. For at least the reasons discussed, there is no *prima facie* case of obviousness.

Reconsideration of claims 1-17, and withdrawal of the obviousness rejection under 35 USC § 103 is therefore requested.

Rejections under 35. USC § 103(a) - Obviousness-type Double Patenting

Claims 1-17 are rejected under the judicially created doctrine of non-statutory double-patenting. Enclosed herewith is a terminal disclaimer of issued US Patent No. 6,613,916. Withdrawal of the double-patenting rejections is therefor requested.

CONCLUSION

The Applicant believes the application is now in condition for allowance. Reconsideration of claims 1-17 and an issuance of a notice of allowance are respectfully requested.

The applicant believes that no extension of time is required; however, this conditional petition is being made to provide for the possibility that the applicant has inadvertently overlooked the need for a further additional extension of time. If any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972.

Respectfully submitted,



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